



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-2711]

Neurodiagnostics and Non-Invasive Brain Stimulation Medical Devices; Public Workshop;
Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following two-day public workshop entitled, “Neurodiagnostics and Non-Invasive Brain Stimulation Medical Devices Workshop”. The focus of the first day of the workshop will be cognitive assessment medical devices, which are intended to provide healthcare professionals with an evaluation of cognitive function through non-invasive measurements. The focus of the second day of the workshop will be non-invasive brain stimulation medical devices, which are medical devices that are intended to improve, affect, or otherwise modify the cognitive function of a normal individual (i.e., without a treatment objective) by means of non-invasive electrical or electromagnetic stimulation to the head. The purpose of this workshop is to obtain public input and feedback on scientific, clinical, and regulatory considerations associated with medical devices for assessing and influencing cognitive function. Ideas generated during this workshop may facilitate further development of guidance regarding the content of premarket submissions

for neurodiagnostics and non-invasive brain stimulation medical devices and help to speed development and approval of future submissions.

Dates and Times: The public workshop will be held on November 19 and 20, 2015, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to:

<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Contact Persons: Hilda Scharen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm 3625, Silver Spring, MD 20993, 301-796-6815, Hilda.Scharen@fda.hhs.gov; or Jay Gupta, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, Jay.Gupta@fda.hhs.gov, 301-796-2795.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by November 6, 2015, at 4 p.m. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, susan.monahan@fda.hhs.gov or 301-796-5661 no later than November 5, 2015.

To register for the public workshop, please visit FDA's Medical Devices Workshops and Conferences calendar at

<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. Select

this meeting/public workshop from the posted events list. Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number.

Those without Internet access should contact Susan Monahan to register (see [Contact for special accommodations](#)). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be available via Webcast. Persons interested in viewing the Webcast must register online by 4 p.m., November 6, 2015. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after November 10, 2015. If you have never attended a Connect Pro event before, test your connection at

https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick

overview of the Connect Pro program, visit http://www.adobe.com/go/connectpro_overview.

(FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the [Federal Register](#).)

Comments: In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is December 5, 2015.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when providing comments to the topics as outlined in section II of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. The address of the Division of Freedom of Information is available on the Agency's Web site at <http://www.fda.gov>. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list).

SUPPLEMENTARY INFORMATION:

I. Background

Cognitive assessment medical devices are intended to provide healthcare professionals with an evaluation of cognitive function through non-invasive measurements. Non-invasive brain stimulation medical devices are intended to improve, affect, or otherwise modify the

cognitive function of a normal individual (i.e., has no cognitive impairment) by means of non-invasive electrical or electromagnetic stimulation to the head. These medical devices both present important safety and effectiveness questions as well as study design and data analysis challenges.

II. Topics for Discussion at the Public Workshop

The workshop seeks to involve industry and academia in addressing scientific, clinical, and regulatory considerations associated with medical devices for assessing and influencing cognitive function. By bringing together relevant stakeholders, which include scientists, patient advocates, clinicians, researchers, industry representatives, and regulators, to this workshop, we hope to facilitate the improvement of this rapidly evolving product area.

This workshop is aimed to address scientific, clinical, and regulatory considerations associated with medical devices for assessing and influencing cognitive function; including, but not limited to, the following topic areas:

- Considerations for clinical study trial designs, patient populations, and patient selection methods;
- considerations for clinical study endpoints, e.g., clinically relevant outcome measures and related statistical analyses;
- identification of risks and risk mitigation strategies; and
- evaluation of prior studies, current clinical research, and available scientific and clinical evidence.

Dated: August 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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